European Standardization Organizations

Welcome to this 10-10 webinar!

Standardization requests – State of play

We start at 10:00 CET

Your webinar moderator

Els Somers

Project Manager

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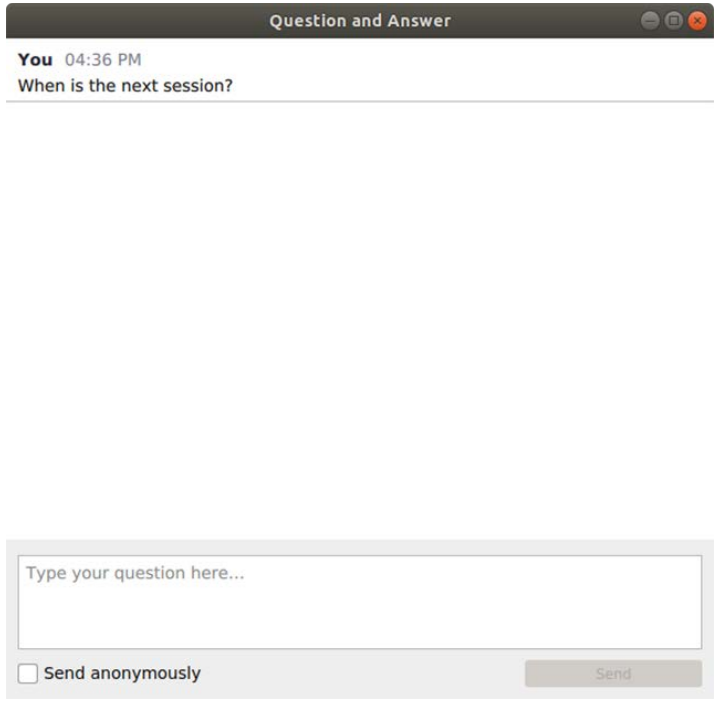
Get the most out of the webinar today

- Use the Q&A panel to submit your questions



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Your speaker today

Alberto SIMEONI

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Main items

The presentation will be FACTUAL and focus on:

- The legislative framework for SReq
- The new model for SReq of the European Commission from 2018
- The SReq process and who has to do what

Acronyms

CoS = Committee on Standards (art. 22 of Reg 1025/2012)

SReq = Standardization Request

SRAHG = Standardization Request Ad-Hoc Group

Standardization Requests

The legislative framework for SReq

from 2013 to 2018
from 2018 to today

2012 - EU Regulation on European standardisation

L 316/12 EN Official Journal of the European Union 14.11.2012

REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 25 October 2012

on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

(Text with EEA relevance)

Art. 10 Standardisation requests to European standardisation organisations

Article 10

Standardisation requests to European standardisation organisations

1. The Commission may within the limitations of the competences laid down in the Treaties, request one or several European standardisation organisations to draft a European standard or European standardisation deliverable within a set deadline. European standards and European standardisation deliverables shall be market-driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and based on consensus. The Commission shall determine the requirements as to the content to be met by the requested document and a deadline for its adoption.

2. The decisions referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 22(3) after consultation of the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation as well as the committee set up by the corresponding Union legislation, when such a committee exists, or after other forms of consultation of sectoral experts.

Art. 10 Standardisation requests to European standardisation organisations

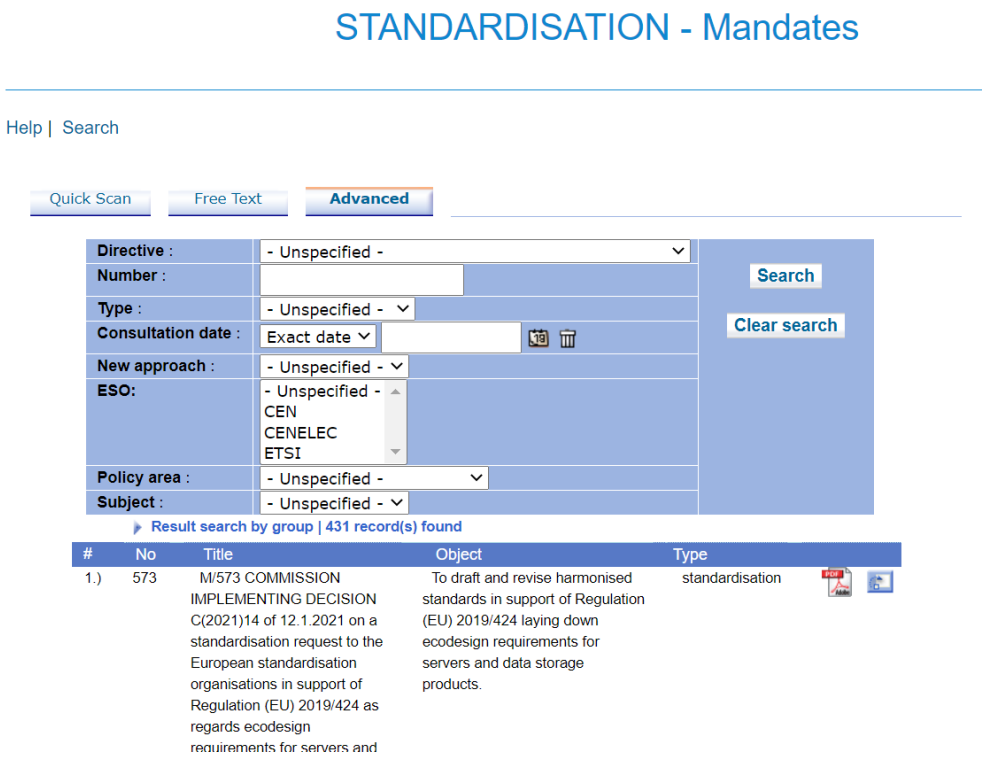
3. The relevant European standardisation organisation shall indicate, within one month following its receipt, if it accepts the request referred to in paragraph 1.

EU Regulation on European standardisation

Before Reg 1025/2012 (1 January 2013) → **Mandates**

After Reg 1025/2012 (1 January 2013) → **Standardization Request**, which is a Commission implementing Decision

EC Database for all Mandates & SReq:
https://ec.europa.eu/growth/tools-databases/mandates



2018 - EC COM(2018) 764 on Harmonised standards

EUROPEAN
COMMISSION

Brussels, 22.11.2018
COM(2018) 764 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market

The reasons for the actions taken by the EC

This Communication provides an overview of the functioning of the European standardisation system and takes stock of the initiatives launched in recent years to support the implementation of the Standardisation Regulation, also in the light of the relevant case law of the Court of Justice of the European Union. The Communication explains the actions taken recently by the Commission to further improve the system and also includes specific actions that the Commission will take in the immediate future in order to enhance the efficiency, transparency and legal certainty for the actors involved in the development of harmonised standards. This Communication is relevant in the context of harmonised standards, that is, European standards adopted on a basis of a request made by the Commission for the application of Union harmonisation legislation.[4]

Since it entered into force in 2013, Regulation 1025/2012 (hereafter 'the Standardisation Regulation')[5] has provided the main legal framework for the European standardisation system including the division of responsibilities and obligations of the actors involved. Certain improvements to the practical implementation of this framework need to be made swiftly, notably in light of the case of law of the Court of Justice of the European Union.

EC changed its internal decision making processes

The Commission is reviewing its internal decision making processes with a view to streamlining the procedures for publishing the references to harmonised standards in the Official Journal[17]. This review is based on best practices within the framework of the Commission's internal rules of procedure and will ensure a co-ordinated, timely and thorough preparation of the necessary decisions.

Second Action: *The Commission is reviewing its internal decision making processes with a view to streamlining the procedures for publishing the references to harmonised standards in the Official Journal.*

[17] As of 1 December 2018, these Decisions will be taken by accelerated written procedure by the Commission.

Citation as a Commission Implementing Decision.

From end of 2018, also the **citation** in the OJEU of the references of harmonised standards has become **a Commission Implementing Decision.**

COMMISSION IMPLEMENTING DECISION (EU) 2019/1956

of 26 November 2019

on the harmonised standards for electrical equipment designed for use within certain voltage limits and drafted in support of Directive 2014/35/EU of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC,

HAS ADOPTED THIS DECISION:

Article 1

The references to harmonised standards for electrical equipment designed for use within certain voltage limits drafted in support of Directive 2014/35/EU,listed in Annex I to this Decision, are hereby published in the *Official Journal of the European Union*.

(1) OJ C 326, 14.9.2018, p. 4.
(4) OJ C 326, 14.9.2018, p. 4.
(5) OJ C 326, 14.9.2018, p. 4.
(6) OJ C 326, 14.9.2018, p. 4.
(7) OJ C 326, 14.9.2018, p. 4.
(8) OJ C 326, 14.9.2018, p. 4.

Standardization Requests

The new model for SReq of the European Commission from 2018

1- Novelty in how requested standards are listed in the SReq

- The SReq contains the list of the requested standards to be provided by the ESOs.
- The list is to be considered **exhaustive** → CEN/CENELEC cannot offer for citation other standards than those listed in Annex 1
- **No flexibility** for ESOs to adapt the work programme.

Example from PPE

Article 1

Requested standardisation activities

The European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are requested to revise existing harmonised standards listed in Table 1 of Annex I to this Decision and to complete the work on the draft standards listed in Table 2 of Annex I to this Decision in support of Regulation (EU) 2016/425 for personal protective equipment by the deadlines set in that Annex.

The standards referred to in the first paragraph shall meet the requirements set out in Annex II.

Annex 1 contains the exhaustive list of standards

Example from PPE

ANNEX I

List of existing standards to be revised and list of draft standards to be completed referred to in Article 1

Table 1. List of existing standards to be revised and deadline for their availability

	Reference information	Date of availability by CEN and Cenelec
1.	EN 140:1998 Respiratory protective devices — Half masks and quarter masks — Requirements, testing, marking	30.4.2024
2.	EN 405:2009 Respiratory protective devices — Valved filtering half masks to protect against gases or gases and particles — Requirements, testing, marking	30.4.2024
3.	EN 1827:2009 Respiratory protective devices — Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only — Requirements, testing, marking"	30.4.2024

Table 2. List of draft standards to be completed and deadline for their availability

	Reference information	Date of availability by CEN and Cenelec
1.	prEN 17109 Ropes courses - Individual safety system - Safety requirements and test methods	30.4.2024
2.	EN 12277:2015/prA1 Mountaineering equipment - Harnesses - Safety requirements and test methods	30.4.2024
3.	prEN 893 rev Mountaineering equipment - Crampons - Safety requirements and test methods	30.4.2024

1- Novelty in how requested standards are listed in the SReq

Example from Medical Devices

Article 1

Requested standardisation activities

1. → The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are requested to revise the existing harmonised standards listed in Table 1 of Annex I to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/745 for medical devices by the deadlines set in that Annex.

2. → CEN and Cenelec are requested to revise the existing standards listed in Table 1 of Annex II to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices by the deadlines set in that Annex.

3. → The standards referred to in paragraphs 1 and 2 shall meet the requirements set out in Annex III.

Annex 1 contains the exhaustive list of standards

Example from Medical devices

ANNEX I

List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(1)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

	Reference information	Deadline for the adoption
1. →	EN 285:2015 Sterilization - Steam sterilizers - Large sterilizers	27 May 2024
2. →	EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	27 May 2024
3. →	EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties	27 May 2024
4. →	EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	27 May 2024

Table 2: List of new harmonised standards to be drafted and deadlines for their adoption

	Reference information	Deadline for the adoption
1. →	Medical gloves for single use - Part 5: Extractable chemical residues (prEN 455-5)	27 May 2024
2. →	Radiation protection - Sealed radioactive sources - Leakage test methods (ISO 9978)	27 May 2024
3. →	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23)	27 May 2024
4. →	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices (ISO 14117)	27 May 2024

ESOs can request EC to add standards

- In the **recital** it is mentioned that ESOs may request EC **to include additional standards**
- The recital and article do not mention what would be the follow up of this request

Example from PPE

(19) In order to enable the Commission to better monitor the requested standardisation work, CEN and Cenelec should provide the Commission with access to an overall project plan containing detailed information on the execution of the standardization request. CEN and Cenelec should promptly inform the Commission if they consider that additional standards would need to be developed or if they consider that more time is necessary for the execution of this request.

ESOs can request EC to modify the deadlines

- In the **recital** it is mentioned that ESOs may request EC to **extend the deadlines** for standards delivery
- The recital and article do not mention what would be the follow up of this request

Example from PPE

(15) It is therefore appropriate to request CEN and Cenelec to revise the relevant existing harmonised standards and to complete the work on the draft standards in support of Directive 89/686/EEC. Those standards should be adopted by CEN and Cenelec by the deadlines set in this Decision. Given that the execution of the request may require more time than initially foreseen, it may be necessary to extend those deadlines taking into account the progress made in the implementation of the work programme prepared by CEN and Cenelec for the execution of the request. It may therefore be necessary to review the respective deadlines accordingly.

2- Novelty in the validity of the SReq

- The European Commission **sets an expiry date** for the SReq.
- It defines the period during which there is a legal framework for the EC to accept standards from the ESOs.
- Once the SReq is expired, there is no legal framework to offer standards, eg. Late delivery – beyond expiry date - are not possible)

Article 5

Validity of the standardisation request

Example from PPE

If CEN or Cenelec do not accept the request referred to in Article 1 within a month of receiving it, the request may not constitute a basis for the standardisation activities referred to in that Article.

This Decision shall expire on 30 April 2024.

The expiry date can be extended

- In the **recital** it is mentioned that ESOs may request EC to extend the expiry date of the Sreq
- The recital and article do not mention what would be the follow up of this request

(22) In order to ensure legal certainty as to the validity of the request after its execution, it is appropriate to provide for a date of expiry of this Decision. Given that the execution of the request may require more time than initially foreseen, it may be necessary to extend the date of expiry taking into account the progress made in the implementation of the work programme prepared by CEN and Cenelec for the execution of the request.

How to amend an existing SReq?

To request additional standards, extension of deadlines for standards' delivery and/or extension of the expiry date of the SReq

→ **CCMC has to contact the relevant EC desk officer**

Take into account that a an existing SReq **can be amended only via a new SReq!** It is not a quick exercise.

Why:
Since the SReq has the legal status of a Commission Implementing Decision, the EC will launch the full process for the approval of a new Commission Implementing Decision, i.e. among others, the EC inter-service consultation and the approval by the Member States in the CoS.

3- Points of attention on the legal requirements for ENs in Annex

Example from PPE

ANNEX II

Requirements for the standards referred to in Article 1

Part A. General requirements for standards listed in Annex I

1. Legal requirements to be supported by the harmonised standards

The harmonised standards shall support application of relevant essential health and safety requirements set out in Annex II to Regulation (EU) 2016/425.

The harmonised standards shall provide detailed technical specifications of essential health and safety requirements, with regard to the design and manufacture of personal protective equipment with the purpose of allowing compliance with relevant essential health and safety requirements.

The structure of a harmonised standard shall be such that a clear distinction can be made between its clauses and sub-clauses which are necessary for compliance with the essential health and safety requirements and those which are not. The essential health and safety requirements shall be taken into account from the beginning and throughout the process of developing of standards.

2. Legal requirements to be covered by an individual harmonised standard

When a harmonised standard does not cover all the essential health and safety requirements, which are applicable to the PPE falling under its scope, the standard shall indicate the essential health and safety requirements applicable to those PPE that are not covered by it. Where a harmonised standard contains technical specifications which do not support application of essential health and safety requirements set out in Annex II to Regulation (EU) 2016/425, such technical specifications shall be clearly distinguished from the specifications

Part B. Specific requirements for revision of existing standards listed in Table 1 of Annex I

1. Requirements for all standards

Standards shall reflect the state of art. CEN and Cenelec shall update the information on the correspondence between the clauses of the standard and the applicable essential safety requirements in standards listed in Table 1 of Annex I.

2. Requirements for specific standards

2.1 Standards on protection against heat and/or fire - PPE constituent materials and other components listed in points **15, 18, 19, 21, 23, 24, 25, 40, 45 and 46** of Table 1 of Annex I

CEN shall revise existing harmonised standards covering constituent materials and other components. The harmonised standard(s) shall describe the technical solutions that are to be applied at the time of design and manufacture of the types of PPE materials and other components which may be accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment to ensure conformity with at least point 3.6.1 of Annex II to Regulation (EU) 2016/425.

2.2. Standards on comfort and effectiveness - PPE protective clothing containing removable protectors listed in points **12, 13, 14, 17 and 20** of Table 1 of Annex I

CEN shall revise existing harmonised standards covering PPE for protective clothing containing removable protectors. The harmonised standard(s) shall describe the technical solutions that are to be applicable at the time of design and manufacture to the type of PPE for

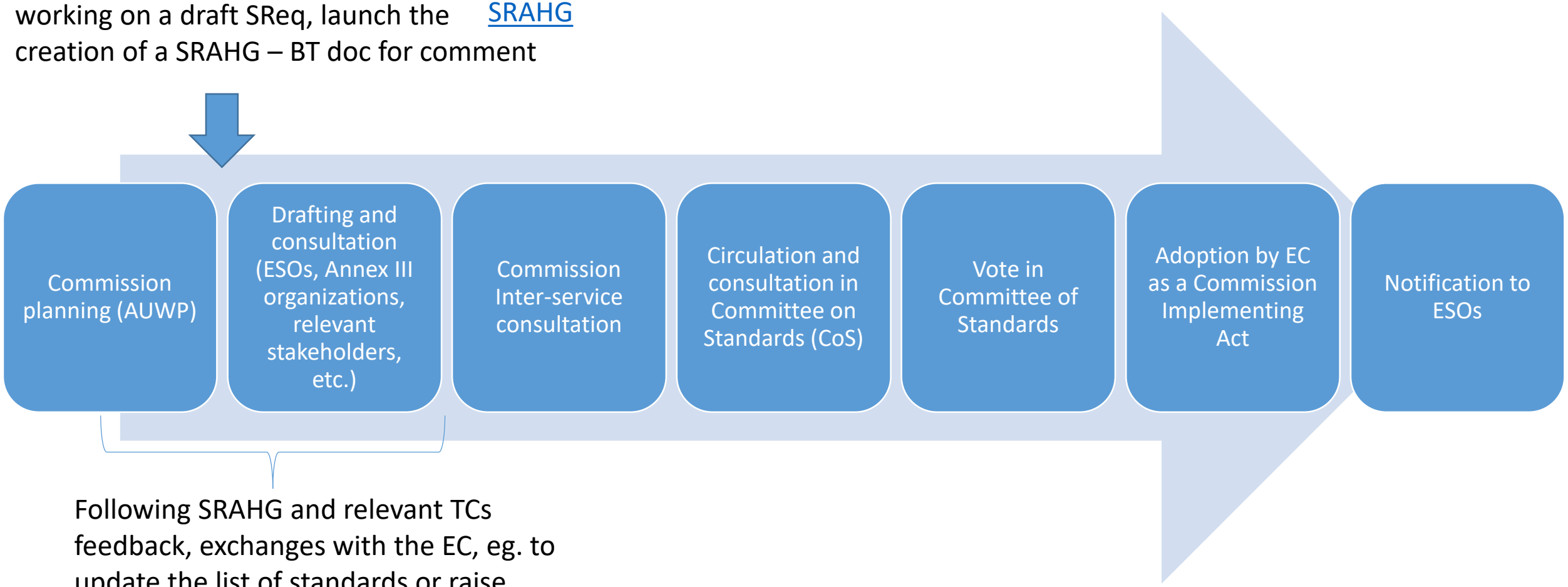
Standardization Requests

The SReq process and who has to do what

SREQ PROCESS I

CCMC as soon as is aware that the EC is working on a draft SReq, launch the creation of a SRAHG – BT doc for comment

SRAHG



Following SRAHG and relevant TCs feedback, exchanges with the EC, eg. to update the list of standards or raise awareness on some aspects of the SReq

BT doc for information and possible reaction
(includes SRAHG creation)

Establishment of the SRAHG

Upon reception of the working draft Standardization Request or in case the EC has expressed the intention to follow up a topic indicated in the Annual Union Work Programme (AUWP), the Sectoral PM announces to BT, the relevant Technical Body(ies) and the relevant Sector Forum and/or Coordination Group the establishment of the SRAHG together with the announcement of the first web-conference and a 'call' for nomination of participants to the SRAHG.

SRAHG composition

Composition of SRAHG

Depending on the complexity of the topic:

- Interested CEN/BT Members and CENELEC Permanent Delegates (or their alternates)
- Experts nominated by CEN/BT Members and CENELEC Permanent Delegates);
- Partner Organizations represented in the Technical Body(ies) including Annex III Organizations (if applicable);
- Representatives of the concerned Technical Body(ies) (if applicable);
- one representative of the relevant Sector Forum and/or Coordination Group (if applicable);
- ISO/IEC representative(s) – when relevant technical work is ongoing at international level (Decisions CEN BT 29/2015 and CENELEC BT D151/061);
- EC representative(s) – when considered necessary to clarify the content/scope of the draft Standardization Request;
- CCMC (including PM assisting for financial support, when relevant).

At any time during the life cycle of the SRAHG, CEN/BT Members and CENELEC Permanent Delegates can join the group and/or nominate experts.

SRAHG objective

6. CCMC sends to the EC the comments agreed at the SRAHG web-conference and inform BT accordingly.

   In its comments to the EC, the Group should carefully cover and assess the following points:

   a. Reasonable deadlines in the SReq,

   b. Key aspects that may affect the technical work to be clearly highlighted,

   c. Ensure that modifications are in track changes between successive versions of the draft Standardization Request (if not already done by the EC).

7. If the SRAHG identifies the need for funding, the template in Annex 2 should be filled out within the shortest delay by the NSBs/NCs (holding the Technical body secretariat(s), if any) requesting funding in order for it to be submitted to the BTWG 217 'Prioritization' for evaluation. This evaluation will be taken for consideration by the SRAHG when submitting their advice on acceptance to the BTs.

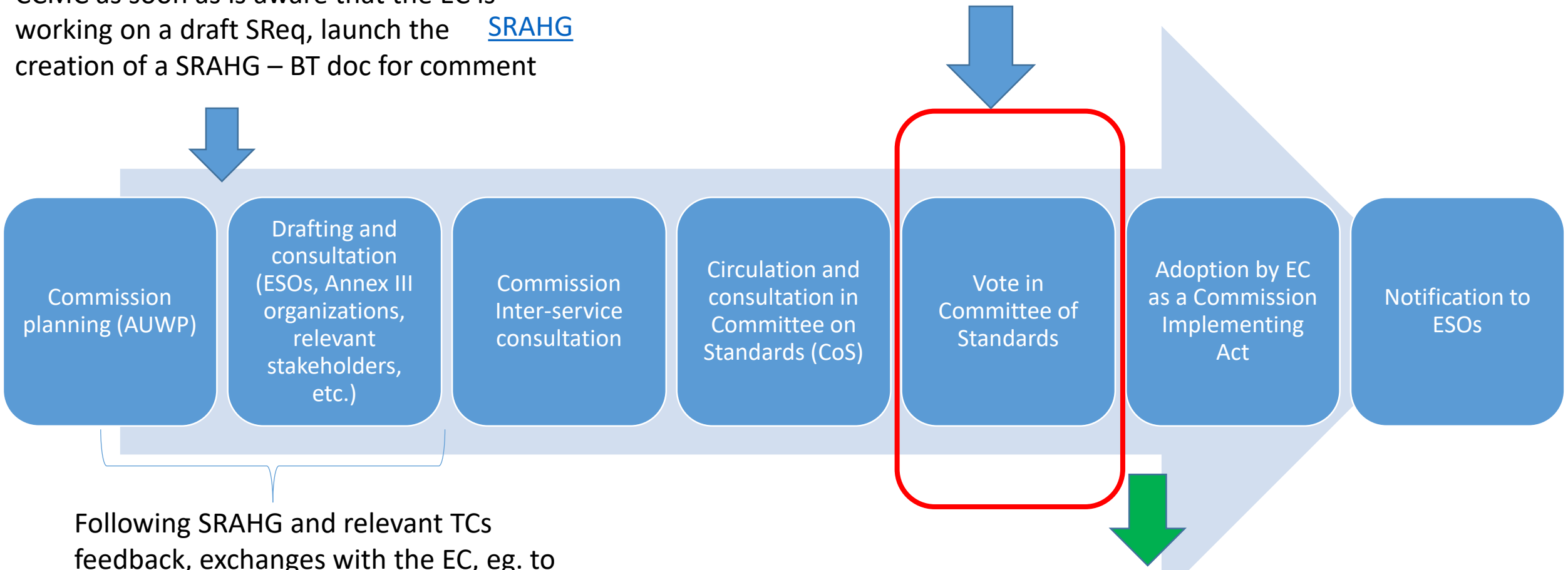
8. Once the (final) draft SReq, as submitted by the EC to the Committee on Standards (CoS), is available, BT takes a decision taking into account the SRAHG position.

SREQ PROCESS II

At the time the vote is launched at CoS, BT Members are informed

CCMC as soon as is aware that the EC is working on a draft SReq, launch the creation of a SRAHG – BT doc for comment

SRAHG



Following SRAHG and relevant TCs feedback, exchanges with the EC, eg. to update the list of standards or raise awareness on some aspects of the SReq

ONLY IF CoS vote is positive, BT Members are requested to decide.
The decision is BASED ON SRAHG recommendation

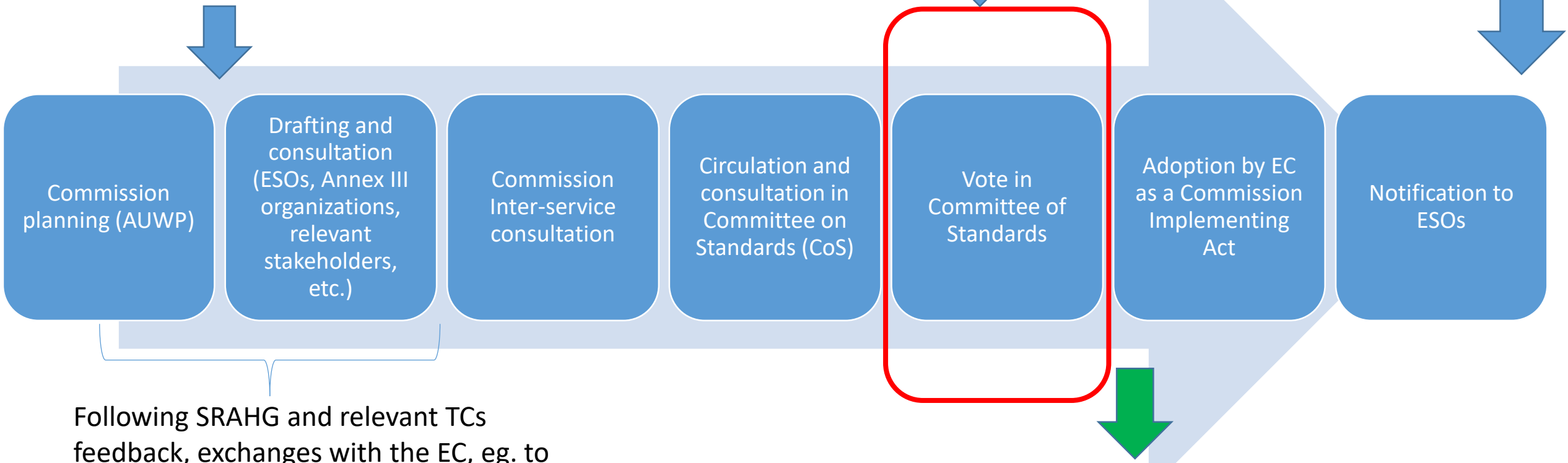
SREQ PROCESS III

CCMC as soon as is aware that the EC is working on a draft SReq, launch the creation of a SRAHG – BT doc for comment

SRAHG

At the time the vote is launched at CoS, BT Members are informed

CCMC sends the letter with acceptance/non acceptance within 1 month



Following SRAHG and relevant TCs feedback, exchanges with the EC, eg. to update the list of standards or raise awareness on some aspects of the SReq

ONLY IF CoS vote is positive, BT Members are requested to decide.
The decision is BASED ON SRAHG recommendation

Important!

1. The analysis of the draft SReq by the SRAHG must be accurate and the recommendation to the Technical Boards must be as clear as possible taking into account the following:

   I. Finally CEN and/or CENELEC – not the SRAHG, not the BTs – formally accept/non accept the Commission Implementing Decision
   II. The acceptance cannot be conditioned to anything (eg. funding, future agreement to change standards/deadlines):

   → if accepted, CEN and/or CENELEC are committed to deliver what is expected in the Sreq

Important!

2. There are **some** elements that can be negotiated with the European Commission in **certain** moments of the process
   → Focus on them at the right moment!

3. The concerned TCs to focus on an **accurate planning** of the expected deliverables to **meet the deadlines** in the SReq
   → The new (flexible) EN process facilitates the planning and monitoring

Relevant Hyperlinks

1. Regulation 1025/2012

   https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF

2. EC COM(2018)

   https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A764%3AFIN

3. EC website on harmonised standards

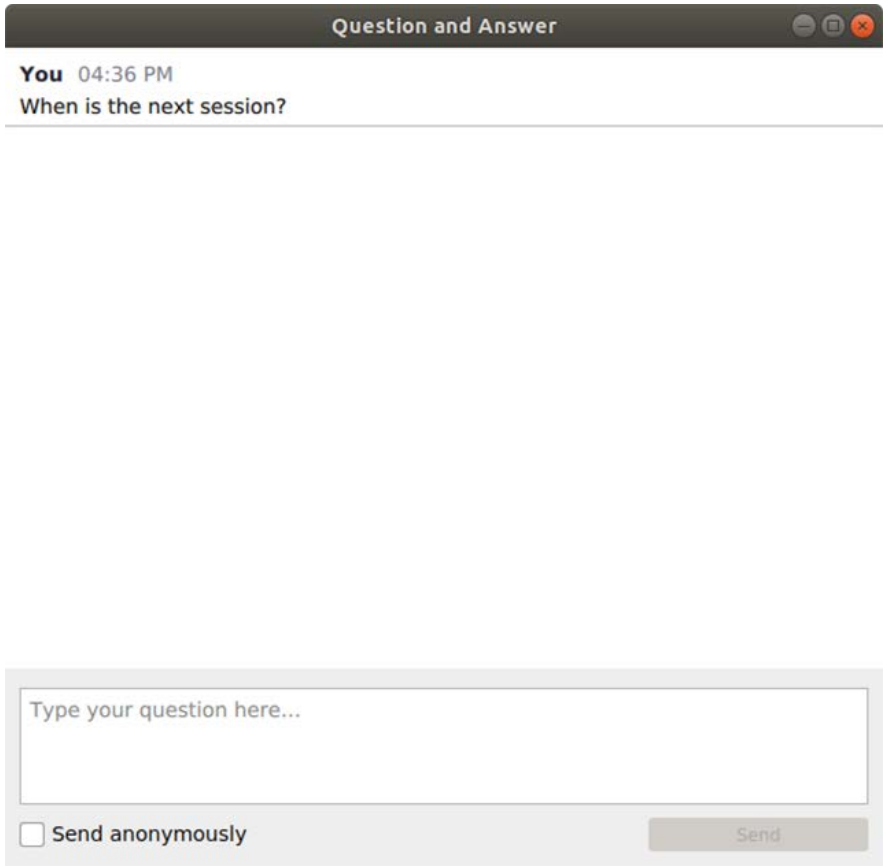
   https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

4. EC mandates database

   https://ec.europa.eu/growth/tools-databases/mandates

Question time

- Use the Q&A panel to submit your questions



European Standardization Organizations

Thank you for your participation!

Next webinar:

2021-03-10 - 10-10 webinar 'Inclusive European Standardization: the case of Gender'